

FEB 11 1997

K964753

## SECTION 1

### SUMMARY OF SAFETY AND EFFECTIVENESS

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1. Device Name : Magnetic Resonance Imaging Accessory
2. Proprietary Name : Matrix 3000 Flexible Spine Coil
3. Classification : Class II
4. Establishment Registration #: 1529041
5. Manufacture Facility Location: USA Instruments, Inc., 675-B Alpha Drive,  
Highland Heights, Ohio 44143, USA  
Telephone: 216-442-5920; Fax: 216-442-5919.
6. Performance Standard: No applicable performance standards have been issued  
under Section 514 of the Food, Drug and Cosmetic Act.
7. Intended Use: The Flexible Spine Coil is a receive-only phased array RF  
coil, used for obtaining diagnostic images of the thoracic  
and lumbar spine in Magnetic Resonance Imaging  
systems. The indications for use are the same as for  
standard MR Imaging. The Matrix 3000 Flexible Spine  
Coil is designed for use with the Outlook (0.23 Tesla)  
MRI scanner manufactured by Picker International Inc.
8. Device Description : ✓ The Flexible Spine Coil consists of two volume RF coil  
elements in a quadrature design. The elements and  
associated circuitry are enclosed in a flexible vinyl  
enclosure housing. The coil is wrapped around the patient  
and the ends are connected and locked. The coil has a  
fixed circumference.

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## 9. Safety and Effectiveness

Parameter	Matrix 3000 Flexible Spine Coil	Predicate
Intended Use	Thoracic and Lumbar Spine Imaging Applications	Flexible Phased Array Spine Coil Picker International (K960497)
Indications for Use	Identical to routine MRI imaging	Flexible Phased Array Spine Coil Picker International (K960497) Profile 7000 C-Spine Coils US ASIA Instruments, Inc. (K943440)
Coil Enclosure Material	Vinyl Fabric	Flexible Phased Array Spine Coil Picker International (K960497)
Coil Design	Two channel receive-only phased array coil	Flexible Phased Array Spine Coil Picker International (K960497)
Decoupling	Switching Diode decoupling	Flexible Phased Array Spine Coil Picker International (K960497) Profile 7000 C-Spine Coils (K943440), US ASIA Instruments, Inc.
Prevention of RF Burns	Does not transmit RF Power  Decoupling isolates the coil elements from RF fields during RF transmission  Coil elements and circuitry are enclosed in a non-conductive housing.	Profile 7000 C-Spine Coils (K943440), US ASIA Instruments, Inc. Flexible Phased Array Spine Coil Picker International (K960497) Same as other Outlook Coils Picker International (K945827)
Radio Frequency Absorption	Coil is a receive only coil and does not transmit RF power.  Power deposition during imaging is limited by SAR algorithm	Profile 7000 C-Spine Coils (K943440), US ASIA Instruments, Inc. Algorithm used on Outlook system (K945827)
Formation of Resonant Loop	Decoupling isolates the coil elements from RF fields during RF transmission  Length of cable and stiffness does not permit looping	Profile 7000 C-Spine Coils (K943440), US ASIA Instruments, Inc.  Flexible Phased Array Spine Coil Picker International (K960497)